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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/630,000	08/01/2000	Bruce Tockman	279.246US1	8111

21186 7590 05/16/2002

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER

KHAN, OMAR A

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 05/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n N .	Applicant(s)	
	09/630,000	TOCKMAN ET AL.	
	Examiner	Art Unit	
	Omar A Khan	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 27-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-15, drawn to structure of a lead, classified in class 607, subclass 115.
 - II. Claims 16-26, drawn to structure of a lead, classified in class 607, subclass 122.
 - III. Claims 28-37, drawn to method of varying the stiffness of a coiled conductor assembly, classified in class 29, subclass 746.
 - IV. Claims 38-42, drawn to method of modifying a stiffness of a lead, classified in class 29, subclass 746.

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require the insulated conductors, including a first and second conductor, to be of a first and second material having different stiffness. The subcombination has separate utility such as a lead apparatus not having a first conductor traverse along less than an entire length of the lead and a second conductor traverse from the proximal end to the distal end of the lead but by having a first and second conductor both traversing the entire length of the lead.

Inventions III and I, II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as

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claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make a materially different product such as a coiled conductor assembly.

Inventions IV and I, II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make a materially different product such as a lead with two or more wound conductors.

Claim 27 links inventions I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 27. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Catherine I. Klima-Silberg on April 25, 2002 a provisional election was made without traverse to prosecute the invention disclosed in claims 16-26. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-15, 27, 28-37, 38-42 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 16-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites the limitations “where the first material...” in line 7 which renders the claim vague and indefinite since the claimed limitation described be “where” is unclear. The examiner suggests –wherein-. Furthermore, Claim 1 is incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the claim is only a listing of elements and does not disclose the structural relationships or connections between the elements defined. Lastly, “coupled with at least one conductor” in line 10 is vague and indefinite as it is not distinctly evident if this is one of the first or second conductors, one of the two or more conductors, or a new element.

Claim 17 is vague for reciting the limitations “at least one conductor” and “at least one other conductor” as it is not clear whether these refer to the first and second, or at least one other conductors cited in the parent claim. Examiner suggest –said at least one conductor-

Claim 18 is vague and indefinite for citing the limitation “one or more conductors” as it is not distinctly clear whether this refers to the conductors cited in the parent claim or a new set of conductors.

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Claim 24 is vague and indefinite for citing the limitation “four conductors” and “two conductors” as it is not clear whether these are the same as or different from conductors cited in the parent claims.

Claim 25 is vague and indefinite for citing the limitation “at least one of the conductors” as it is not clear whether this is the same as or different from conductors cited in the parent claim.

Claim 26 is vague and indefinite for containing the phrase “the conductors” as it is not distinctly clear which one or all of the conductors in the parent claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 16-20 and 23-26 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Van Venrooij (U.S. Patent No. 5,849,032).

4. Claims 16-20, 23 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Carner (U.S. Patent No. 6,253,111). The silver core of first outer conductor 48 is considered to be an insulated conductor comprised of a material having different stiffness and electrical properties than second and third conductors 44 and 46 made of MP35N. In addition, it is noted

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that the claims state that the conductors are “comprised” (an open-ended limitation) of a first and second material and do not prevent the conductors from using the same materials.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Venrooij (U.S. Patent No. 5,849,032). Van Venrooij discloses all of the claimed limitations but does not disclose expressly the first material comprising MP35N and the second material comprising Pt/Ta. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use MP35N and Pt/Ta as the materials for the first and second conductors respectively, because applicant has not disclosed that using MP35N and Pt/Ta for the first and second materials provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with Van Venrooij, which teaches the use of differing materials (nitinol and MP35N) with obviously different stiffness providing for selectively variable lead stiffness depending on the relative locations of the conductors with different stiffness. Therefore, it would have been an obvious matter of design choice to modify Carner to obtain the invention as specified in claims

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6. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carner (U.S. Patent No. 6,253,111) in view of Kruse et al. (U.S. Patent No. 5,995,876). Carner discloses all of the claimed limitations but does not expressly speak to a lead body with four conductors disposed at the proximal end and two conductors disposed at the distal end of the lead body. Kruse teaches an implantable electrode lead with four conductors disposed at the proximal end and two conductors disposed at the distal end of the lead body for positioning one or more electrodes proximal to the tip electrode located at the distal end of the lead body. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the implantable electrode lead of Carner by including four conductors at the proximal end and two conductors at the distal end of the implantable electrode lead for including electrodes, in addition to tip electrodes, located in a proximal position.

7. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carner (U.S. Patent No. 6,253,111) in view of Fischer, Sr. (U.S. Patent No. 6,083,216). Carner discloses all of the claimed limitations but does not explicitly speak to at least one of the conductors formed of material having heat setting capabilities. Fischer teaches an implantable, multi-electrode lead with several conductors and a torque coil made from thermally setting material disclosed as being used as a conductor for using the thermally setting properties of the torque coil to affect a semi-permanent shape to the implantable electrode lead. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the implantable electrode lead of Carner by using one or more conductors made of thermally setting material, as taught by Fischer, for imparting a semi-permanent shape to the implantable electrode lead.

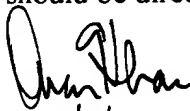
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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Omar A Khan whose telephone number is (703) 308-0959. The examiner can normally be reached on M-F 9AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0873.


5/6/2002
Omar A Khan
May 6, 2002


GEORGE R. EVANISKO
PRIMARY EXAMINER

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